

MANUFACTURING & LABELING CHECKLIST

PROCESS/LABEL REVIEW INFORMATION

RETURN TO: MONTANA FOOD, DRUG & COSMETICS PROGRAM

COGSWELL BLDG RM C214

PO BOX 202951

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Phone (406) 444-5306

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The following questions should be answered about your product. If the question does not apply to your particular product write "N/A" and if not obvious, then tell why it does not apply. If you have questions about the meaning of some questions please feel free to call us at the above number. Incomplete submittals may be returned.

NAME OF MANUFACTURING/PROCESSING ESTABLISHMENT

NAME OF OWNER CORPORATION

CONTACT PERSON _____ EMAIL, IF ANY _____

STREET ADDRESS OF POINT OF MANUFACTURE

MAILING ADDRESS (if different) _____

CITY _____ STATE _____ ZIP _____

TELEPHONE # (____) - _____

FAX # (____) - _____

IS THIS PRODUCT INTENDED TO BE A: (Check one)

FOOD PRODUCT _____ DIETARY SUPPLEMENT _____ COSMETIC _____ DRUG/MEDICATION _____

COMMON NAME FOR THE PROPOSED PRODUCT _____
(i.e. - "Pancake mix") Wine

YOUR TRADE NAME FOR THE PRODUCT _____
(i.e. - "Blue Mountain Buckwheat Pancake Mix")

IS THE PROCESSING CONFINED TO REPACKING? _____ YES _____ NO (Repacking is a process in which large containers of food are repacked into retail size packages, i.e. 100# sacks of beans repacked as 1# packages.

WILL THERE BE ON-SITE RETAIL SALES? _____ YES _____ NO

WILL THE PRODUCT BE SOLD WHOLESALE (case lots) FOR RE-SALE ELSEWHERE? _____ YES _____ NO

WHAT STORES WILL BE CARRYING THE PRODUCT _____

WILL THE PRODUCT BE SOLD VIA THE INTERNET? Yes _____ No _____

WILL THE PRODUCT BE SOLD ONLY IN MONTANA? _____ OUTSIDE MONTANA (INTERSTATE) _____

LIST ALL INGREDIENTS IN DESCENDING ORDER OF PREDOMINANCE BY WEIGHT, AND THE WEIGHTS AND MEASURE OF EACH PER BATCH, IDENTIFYING BATCH SIZE BELOW.

BATCH SIZE _____

BATCH WEIGHT _____

INGREDIENT

MEASURE PER BATCH

WEIGHT PER BATCH

LIST ALL COMPONENTS THAT HAVE INGREDIENTS WITHIN THE INGREDIENTS IN PARENTHESES
Mayonnaise (egg yolks, vegetable oil, lemon juice, salt, vinegar, oxystearin...)

(A copy of page 2 is needed for each variation, including label exhibit. For example--one set for blueberry muffins, and another set for poppy seed muffins, and another for brownies, etc. Photocopy p. 2 as needed or include recipe sheets that provide equivalent details)

ARE ANY RESTRICTED INGREDIENTS TO BE USED OR ALREADY IN YOUR PRODUCT (*Sulfites, sweeteners, MSG flavorings*)? YES _____ NO _____ IF YES, LIST HERE _____

LIST ALL FOOD COLORINGS, WHETHER ADDED DIRECTLY OR CONTAINED WITHIN INGREDIENTS USED IN THE PRODUCT (*ingredients within ingredients*).

ARE ANY ORGANIC CLAIMS BEING MADE? YES _____ NO _____ IF YES, THEN ATTACH CERTIFICATION COPIES OR OTHER DOCUMENTATION FROM THE MONTANA DEPARTMENT OF AGRICULTURE.

ARE ANY OTHER CLAIMS BEING MADE SUCH AS "PURE", "NATURAL" "LIGHT", "LOW CHOLESTEROL", "LOW FAT", "REDUCED SALT", ETC? YES _____ NO _____ IF YES, ATTACH DOCUMENTATION. IF A NUTRITIONAL CLAIM IS MADE, YOU MAY NOT USE THE EXEMPTION FROM **NUTRITION FACTS** LABELING.

IS NUTRITIONAL LABELING INFORMATION BEING INCLUDED? YES _____ NO _____ IF YES, ATTACH DOCUMENTATION, OR EXPLANATION.

NOTE: Nutrition labels required after May 1994, with some exceptions - including small business producing less than 10,000 units last year and having fewer than 50 employees, if no label claims are made or implied. For further description of NLEA exemption see, or call us at the number given above.)

WILL THE PRODUCT LABEL SPECIFY REFRIGERATION? YES _____ NO _____

WILL THERE BE AN "OUT DATE" OR "BEST IF USED BY ..." DATE? YES _____ NO _____

IF THE PRODUCT IS TO BE WHOLESALED (OFFERED AT OUTLETS AWAY FROM THE MANUFACTURING FACILITY), INCLUDE INFORMATION ON WHAT QUALITY CONTROL PROCEDURES YOU WILL USE.

DESCRIBE IN DETAIL YOUR MANUFACTURING PROCESS: INCLUDE TIMES, TEMPERATURES OF COOKING PROCESS IF APPLICABLE, SOURCE OF PRINCIPAL INGREDIENTS & ALSO DESCRIBE SET UP PROCEDURES, FINISHED PRODUCT HANDLING, CLOSURES, PRODUCTION CODES OR DATE CODES, SHELF LIFE, QUALITY CONTROL OR TESTING PROCEDURES ETC. *(Use additional sheets if necessary)*

PACKAGING MATERIAL, CONTAINER CLOSURES: *(describe)*

LABELS - LABELING REVIEW & APPROVAL IS REQUIRED PRIOR TO LICENSING. AN ACTUAL SIZE LABEL EXHIBIT IS NEEDED FOR THIS PURPOSE. A CLEAR PHOTOCOPY WILL DO.

ATTACH PRINTERS PROOF OR PHOTOCOPY OF PROPOSED LABEL HERE, OR ON A SEPARATE SHEET. ➡

IF THIS IS A NEW FACILITY, HAVE YOU CONTACTED THE LOCAL HEALTH DEPARTMENT FOR APPROVAL AND INSPECTION OF YOUR FACILITY? YES _____ NO _____

NAME OF THAT DEPARTMENT _____

WHO DID YOU TALK TO THERE _____

DID YOU HAVE A CURRENT "*Food Purveyor License*" ISSUED BY THE DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES (*FOOD & CONSUMER SAFETY*)? YES _____ NO _____

IF YES, GIVE NAME ISSUED UNDER: _____

AND THE NUMBER OF THE LICENSE: F _____

AND THE ENDORSEMENT TYPE (F1, F2, F6, F13 ETC): _____

AND THE COUNTY IN WHICH LICENSE WAS ISSUED: _____

AND THE PRODUCT CODES APPROVED (IF ANY): _____

CANNED FOODS

LOW ACID CANNED FOODS 1) Have pH greater than 4.6 and water activity greater than 0.85, 2) are sealed in a hermetic (*air-tight*) container, 3) receives heat treatment for the purpose of achieving commercial sterility, 4) and is normally stored under non-refrigerated conditions.

AN **ACIDIFIED FOOD** is a low acid food to which acid(s) or acid food(s) are added. It has a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. An acidified food is normally stored and distributed under non-refrigerated conditions. (*Carbonated soft drinks are not acidified foods.*)

IF YOU MEET EITHER OF THE ABOVE CRITERIA YOU MUST HAVE AN FDA APPROVED SCHEDULED PROCESS, CERTIFICATION OF APPROPRIATE TRAINING, AND YOU MUST REGISTER YOUR PRODUCT AND FACILITY WITH THE FDA (*FOOD & DRUG ADMINISTRATION*). IF APPLICABLE ARE YOU REGISTERED WITH FDA?

N.A. _____ YES _____ NO _____

WATER BOTTLERS

IF YOUR PRODUCT IS WATER, HAVE YOU CONTACTED THE DRINKING WATER PERMIT SECTION OF THE MONTANA DEPARTMENT OF ENVIRONMENTAL QUALITY (*DEQ*)?

YES _____ NO _____ N/A _____

DATE _____ CONTACT PERSON _____

HAVE PLANS BEEN SUBMITTED TO THAT AGENCY AND APPROVED?

YES _____ NO _____ PWS NUMBER ISSUED _____

DESCRIBE THE SIZE OF CONTAINERS OR BOTTLES YOU WILL BE USING:

PRIOR APPROVAL AND A PWS NUMBER ARE REQUIRED PRIOR TO LICENSING. PRODUCTION CODING/DATE CODING ARE REQUIRED FOR BOTTLED WATER.

INCLUDE A SCHEMATIC OF THE WATER TREATMENT, CONTAINER STORAGE PLANS, BOTTLING EQUIPMENT, LABELS, COPIES OF THE CHEMICAL ANALYTICALS, AND OTHER DETAILS AS ATTACHMENTS TO THIS FORM.

IF YOU ARE PACKING OR BOTTLING WATER FROM A SOURCE OTHER THAN YOUR OWN (CO-PACKING FOR ANOTHER FIRM) THE ANALYTICALS FOR THEIR WATER MUST BE REVIEWED AND APPROVED PRIOR TO BOTTLING. IF YOU ARE BOTTLING YOUR WATER UNDER DIFFERENT SPONSOR LABELS, PLEASE INCLUDE LABEL EXHIBITS AS APPROPRIATE.